

REMARKS

The title has been changed merely to describe more aptly the invention as now claimed.

Claims 34-37 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Chin '477 in view of Kieturakis '183, further in view of Hildwein et al '156. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, independent claim 34 has been amended merely to define the method with greater particularity, and as amended now recites "inserting the rigid endoscopic cannula disposed within the expendable sheath into the incision," and "advancing the endoscopic cannula with the expandable sheath disposed thereon through tissue under endoscopic visualization to form a passage of dissected tissue between the incision and the pericardium," and "laterally expanding the sheath within the passage responsive to withdrawing the endoscopic cannula through the expandable sheath in a direction toward a proximal end thereof to form a working cavity in dilated tissue along the passage."

In addition, the dependent claims are further restricted by specific recitations of "laterally expanding the sheath responsive to the distal tip withdrawing with the endoscopic cannula through the expandable sheath in a direction toward the proximal end thereof, leaving the expandable sheath positioned in the passage" or "additionally dilating the working cavity to larger lateral dimensions than the

greater diameter of the distal tip on the endoscopic cannula responsive to insertion into the expandable sheath positioned within the passage of surgical tools having dimensions larger than the greater diameter of the distal tip on the endoscopic cannula," or "inserting into a proximate end of the expandable sheath positioned within the passage a surgical tool for performing a cardiac procedure in which the surgical tool has a maximal lateral dimension greater than a maximal lateral dimension to which the sheath expanded in response to withdrawal therethrough of the distal tip of the endoscopic cannula" and "advancing the surgical tool within the expandable sheath positioned within the working cavity toward a distal end thereof to laterally expand the expandable sheath and additionally dilate tissue in the working cavity."

These aspects of the claimed invention greatly facilitate forming a passage through tissue under endoscopic visualization, and then dilating surrounding tissue about the passage as the endoscope is withdrawn from the expandable sheath that remains positioned in the passage. The sheath thus remains as a pathway guide in the passage for convenient insertion and removal of surgical instruments therethrough as an aid to reducing abrasion or other frictional trauma to tissue surrounding the passage. Significantly, the expandable sheath is positioned simultaneously with penetration of tissue under endoscopic visualization to reduce tissue trauma and to help avoid surgical error.

These aspects of the claimed invention are not disclosed or suggested by the cited references considered either alone or in the combination proposed by the Examiner. It is noted that Chin et al '477 discloses penetrating tissue between the ribcage R and the diaphragm D with exposed or unprotected forceps and scalpel, with concomitant risk of unintended tissue trauma.

And, Kieturakis '183 is noted to provide fiber-optic visualization, through a surgical dissector that might be considered to carry an expandable sheath. However, neither of these references either alone or in combination presents any suggestion or motivation for leaving an expandable sheath positioned within a passage through dissected tissue in any manner resembling Applicant's claimed invention.

Thus, combining the references with Hildwein et al '156, which merely penetrates intercostal tissue, without visualization, to install a trocar or surgical port fails both alone and in the combination of references to provide any incentive or instruction for inserting an expandable sheath disposed on an endoscope to provide endoscopic visualization, and then laterally expanding the expandable sheath in response to withdrawal of an endoscope therefrom. It is therefore respectfully submitted that the Examiner's proposed combination of references includes no teaching or suggestion supporting the combination, and fails to establish even a *prima facie* basis, including all recited steps, from which a proper determination of obviousness may be made. MPEP § 2142. Nor can there be even

a reasonable expectation that the Examiner's proposed combination of the cited references would be successful or yield any method resembling Applicant's claimed invention.

And, Applicant submits that it is improper to extract and combine bits and pieces of disclosures from numerous references without any teaching or motivation found in the cited art for doing so.

The Examiner cannot establish obviousness through references describing various aspects of Applicant's invention unless the Examiner also provides evidence of motivating force to impel a person skilled in the art to do what Applicant has done. *Ex parte William C. Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993). At best, the Examiner's comments regarding obviousness of the claims amounts to an assertion that one of ordinary skill in the relevant art would have been able to arrive at Applicant's claimed invention [given the individual disclosures of the cited references] because he had the necessary skill to carry out the requisite combination. This is an inappropriate standard for obviousness. *Ex parte William C. Levengood*. And, as the Federal Circuit has held, "Before the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestions for doing so." *In re Rita S. Jones, et al.*, 958 F.2d 347; 21 USPQ2d 1941 (Fed. Cir. 1992).

The suggestion to modify or combine references must be found in the references themselves, and not in the Applicants' disclosure. MPEP § 2143 (citing

In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).) Resorting to hindsight in light of Applicants' disclosure is not permissible. MPEP § 2142. Under no conditions can the Examiner combine teachings or references, unless those references include some teaching or suggestions supporting the combination. *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992); (quoting *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).)

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some *teaching, suggestion or incentive* supporting the combination," where the prior art of record should provide the suggestion or incentive. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) (emphasis added).

It is therefore respectfully submitted that claims 34-37 as amended are now patentably distinguishable over the cited art.

Rejected claims 24 and 40 have been cancelled without prejudice.

Entry of this amendment, which is submitted to condition this application for allowance, is respectfully requested. In the event the Examiner elects to continue the rejection of claims, he is requested to enter this amendment in order to clarify and simplify the issues for appeal. And, the Examiner is invited to contact the undersigned attorney for the Applicant regarding any remaining issues that may expedite favorable disposition of this application.

Respectfully submitted,
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